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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/757,863	01/15/2004	Leonard Presta	P1726R1D1	5958

9157 7590 05/22/2006

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EXAMINER	
CROWDER, CHUN	
ART UNIT	**PAPER NUMBER**
1644	

DATE MAILED: 05/22/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/757,863	PRESTA, LEONARD	
	Examiner	Art Unit	
	Chun Crowder	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 March 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1, 3-20* is/are pending in the application.

4a) Of the above claim(s) *12 and 13* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1, 3-11 and 14-20* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETATILED ACTION

1. Applicant's amendment, filed 03/08/2006, is acknowledged.

Claim 2 has been canceled.

Claim 1 has been amended.

Claims 15-20 have been added.

Claims 1 and 3-20 are pending.

Claims 12 and 13 have been withdrawn from further consideration by the examiner, 37 C.F.R. 1.142(b) as being drawn to a nonelected invention.

Claims 1, 3-11, and 14-20 are currently under consideration.

2. It is noted that the newly added claims 15-20 have introduced new species, therefore, a new Species Election requirement is set forth as following:

Species Election

3. This application contains claims directed to the following patentably distinct species of the claimed invention.

Applicant is required to elect a method of for treating a disorder by administering a variant of a parent antibody polypeptide wherein:

A) the variant binds one specific molecule (e.g. CD20 as recited in claim 15), **AND**

B) the method is for treating one specific cancer (e.g. lymphoma as recited in claim 19).

These species are distinct because methods of treating different disorders with antibodies bind to different cell surface molecules differ with respect to one or more of ingredients, method steps and/or endpoints. Furthermore, the examination of the different ingredients, method steps and/or endpoints would require different searches in the scientific literature. As such, it would be burdensome to search these Species together.

Applicant is required under 35 USC 121 to elect a single disclosed species to which the claims would be restricted if no generic claim is finally held to be allowable.

4. Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. § 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. M.P.E.P. § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.

5. Upon consideration of the teachings of the prior art and in the interest of compact prosecution, the prior art search has been extended to include all species.

6. Applicant's IDS, filed 11/01/2005, 02/13/2006, and 03/21/2006, is acknowledged and considered.

7. The Office Action will be in response to applicant's arguments, filed 03/08/2006. The rejection of record can be found in the previous Office Action, mailed 10/11/2005. The text of those sections of Title 35 U.S.C. not include in this Action can be found in a prior Action.

8. Claims 1, 3, 4, 8-11, and 14 stands rejected and newly added claims 15-20 are rejected under **35 U.S.C. 102(e)** as being anticipated by US Patent No: 6,528,624 (claims priority of provisional application No: 60/080,477, filed 04/02/1998, Reference No 16 cited in IDS).

Applicant's arguments have been fully considered by have not been found convincing.

Applicant argues that the Example 3 on columns 41-44 of the '624 Patent is first included in the provisional application USSN 60/116,100 filed 01/15/1999, while the instant application claims priority to USSN 60/116,023 filed 01/15/1999, therefore, the '624 Patent does not constitute to be a prior art to the instant application.

This is not found persuasive for the following reasons:

Contrary to applicant's assertion, in addition to USSN 60/116,100, the '624 Patent claims priority to an additional provisional application USSN 60/080,447, filed 04/02/1998, that has support for the teachings of making antibody variants comprising a human IgG Fc region with amino acid modification in Fc regions including positions at 334 (see entire document, particularly Table 2 on column 41) which, in turn, provide sufficient support for relying on the '624 Patent as 102(e). The '624 Patent further teaches that molecular targets for the antibody variants can be selected to make the antibodies include CD20 and HER2 (e.g. see column 18-2). Furthermore, the '624 Patent teaches that the antibody variants can be applied for in vivo uses such as treatment of diseases including cancer where the polypeptide variant binds the HER2 receptor or CD20 (e.g. see columns 34-36).

It is noted that under 35 U.S.C. 102(e), the entire disclosure of a US Patent or an patent application when examining a PG-PUB application having an earlier filing date can be relied on to reject the claims. See MPEP 2136.02.

Therefore, the teachings of the '624 Patent anticipate the claimed invention.

9. Claims 1, 3-11, and 14 stand rejected and claims 15-20 are rejected under **35 U.S.C. 112, first paragraph**, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention for reasons of record set forth in the previous Office Action mailed 10/11/2005.

Applicant's arguments have been fully considered by have not been found convincing.

Applicant argues that the claim 1 does not require that ADCC be formally proven in a patient, and that one could practice the claimed invention without having to demonstrate that ADCC was operating in patients.

Contrary to applicant's assertion, the instant invention is not limited to more effective ADCC in patients or in vitro. It is further noted that during patent examination, the pending claims must be given the broadest reasonable interpretation consistent with the specification. Claims terms are interpreted not only in light of the specification but also in light of the prior art. See In re Cortright, 49 USPQ2d 1464, 1467 (Fed. Cir. 1999).

Further, even in the cases that the host effector mechanisms to monoclonal antibody activity (e.g. Herceptin) are evaluated in vivo, the results often cannot simply be used to predict clinical efficacy because monoclonal antibodies behave differently in different experimental systems, thus even the data from in vivo animal experiments do not translate to therapeutic effect in heterogeneous human cancer patients (Eccles, Breast Cancer Res. 2001, 3:86-90, see entire document, particularly pages 87-88, and Tutt et al. The Journal of Immunology, 1998, 161:3176-3185. See entire document, particularly pages 3180-3184).

In addition the specification does not reasonably provide enablement for method of treating any disorder by administering the antibody variants The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

10. Upon reconsideration, including applicant's amendment, the previous ***written description*** **rejection** has been withdrawn.

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chun Crowder whose telephone number is (571) 272-8142. The examiner can normally be reached Monday through Friday from 8:30 am to 5:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Chun Crowder, Ph.D.
Patent Examiner
May 4, 2006

PHILLIP GAMBEL, PH.D
PRIMARY EXAMINER
1600
5/8/06